K011143

MAY 2 9 2001

510(k) Summary

Introduction

According to the requirements established in the Food and Drug Administration's guidance document entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-3544

Contact Person: Kay A. Taylor

Date Prepared: April 12, 2001

2) Device name

Proprietary name: Tina-quant D-Dimer Test System
Common name: D-Dimer Test
Classification name: Fibrinogen/Fibrin Degradation Products Assay

3) Predicate device

We claim substantial equivalence to the currently marketed Tina-quant D-Dimer Test System on Roche Hitachi (K002706).

510(k) Summary, Continued

4) Device Description

The Tina-quant D-Dimer Test System is based on a particle enhanced immunoturbidimetric assay. Human D-Dimer agglutinates with latex particles coated with anti-D-Dimer antibodies. The precipate is determined turbidimetrically.

5) Intended use

For the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers.

6.) Substantial equivalence

The table below indicates the similarities between the modified Tina-quant D-Dimer Test System on Integra analyzers and the predicate, Tina-quant D-Dimer Test System on Hitachi analyzers (K002706). In summary, the Tina-quant D-Dimer Test System described in this submission is, in our opinion, substantially equivalent to the predicate device.

Comparison of Proposed and Predicate Device

Topic	Modified Tina-quant D-Dimer	Tina-quant D-Dimer (cleared K002706)
Intended Use	Same	For the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers.
Indication for Use	Same	Aid in detecting the presence and degree of intravascular coagulation and fibrinolysis and in monitoring therapy for disseminated intravascular coagulation.
Sample Type	Same	Human plasma
Analytical Sensitivity	<0.08 µg/ml	0.04 µg/ml
Wavelength	660 nm	800nm
Ratio Plasma/R1/R2	1/18/18	1/17.85/17.85
Measuring Range	Same	0.15-9.0 µg/ml

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 9 2001

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K011143
Trade Name: Roche Diagnostics Tina-quant® D-Dimer Test System
Regulation Number: 21 CFR § 864.7320
Regulatory Class: II
Product Code: GHH
Dated: May 9, 2001
Received: May 14, 2001

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K011143
Device Name: **Tina-quant D-Dimer Test System**

Indications for Use:
For the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers. Aid in detecting the presence and degree of intravascular coagulation and fibrinolysis and in monitoring therapy for disseminated intravascular coagulation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Larry J. Bramhall (acting)
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011143